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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,015	11/19/2008	Tami Harel	298859-00012	3153

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EXAMINER	
STICE, PAULA J	

ART UNIT	PAPER NUMBER
3766	

NOTIFICATION DATE	DELIVERY MODE
09/27/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipmail@eckertseamans.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,015	HAREL ET AL.	
	Examiner	Art Unit	
	PAULA J. STICE	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-77* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-77* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *18 September 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/18/2011; 12/22/2009; 11/04/2009; 10/15/2008; 07/27/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

IDS

1. Applicant should note that the large number of references in the attached IDS have been considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed provisional application, Application No. 60/448,964, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. For instance in claim 1, the claim requires "a first subset" and "a second subset", the

specification of 60/448,964 discusses sets however no discussion of subsets or how they would be used is supplied. With respect to claims 33, 34 and 35 the orientations provided by these claims and their benefit over prior art, is not disclosed in 60/448,964.

As an added note, benefit will be given to the PCT filed 3/18/2005 in that the applications seem to disclose the same general invention.

As a genera note, the application claims priority to 60/488,964 dated Mar. 18, 2004 (see paragraph [0002]), this date is inconsistent with the PTO records. The date should be 3/21/2003. However, this is, as it stands a moot point in that the priority date is not being afforded in that there is a lack of support for the independent claims within the earlier filed provisional application.

Information Disclosure Statement

3. Applicant should note that the large number of references in the attached IDS have been considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claim 1: The claim recites "implantation site", in line 2, and "the site" in lines 4 and 5. The electrode delivery a signal to "the site" to treat obesity and reduce blood glucose. It is unclear how **the same site** can have stimulation from two subsets of electrodes, presumed to be different, in order to perform two very distinct purposes (i.e. treat obesity and lower blood sugar).

7. Regarding claims 16-21, 33-35 and 36-77: the claims recite either; "an axis of the stomach" or "the axis of the stomach", this claim limitation is indefinite in that there are infinite axes of any structure, the axis must be in relation to something in order to have any useful meaning. The claims are therefore indefinite in that it is not discernable what "an axis of the stomach" is or might be. These claims will not be rejected with identical prior art in that it is unclear as to what the claim limitation, central to the claim set, is directed towards.

8. Regarding claims 23 and 26-28 and 45-47, 59-61 and 73-75: the claims recite a "pacing pulse", however within this apparatus claim there is no component, electrode or other component which is disclosed as delivering a pacing pulse, it is unclear how the pacing pulse is delivered, to what structure it is delivered or what it is. There could be a cardiac pacing pulse, or some other kind of pacing pulse. Furthermore, it is unclear what is being paced. Due to the lack of clarity prior art rejections will not be made against these claims in that it is unclear how the apparatus can deliver a pacing pulse to either reduce blood glucose or treat obesity as directed by claim 1.

9. Regarding claims 27, 46, 60 and 74: the claims recite "refractory period of the implantation site induced by the pacing pulse", however there are no sensing electrodes

disclosed in the claims which could determine a refractory period, furthermore there is no manner in which a refractory period is determined. The claims are therefore indefinite in that it is unclear when or how a refractory period is determined.

10. The remainder of the claims are also rejected in that they depend from previously rejected independent claims.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-7, 9-12, 16-21 and 33-39, 50-52, 53 and 64-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Flesler et al. (US 6,600,953 in IDS).

13. Regarding claim 1 and generally claims 16-21 and 33-37, 50-51 and 64-65 (as understood): Flesler discloses a set of electrodes (30 Figs. 1A, 1B and 200 of Fig. 4) adapted to be implanted at an implantation site in a patient, a control unit 90/190 (Figs. 1A, 1B, 4) adapted to drive a first subset of the set of electrodes to apply a signal to the site configured to reduce a blood glucose level and to drive a second subset of the set of electrodes to apply a signal to the site configured to treat obesity of the patient (Col. 3, lines 65-67 through Col. 4, lines 1-7). By means of explanation, the stomach and intestinal apparatus are disclosed as being used together (Col. 14, lines 6-8 and Col. 15, lines 1-8).

14. Regarding claims 2-3: Flesler discloses that the control unit is adapted to drive the first subset and/or second subset as an ETC signal (Col. 2, lines 20-25 and Col. 3, lines 55-67 through Col. 4, lines 1-7).

15. Regarding claim 4: Flesler discloses at least one electrode in common, the sensing electrodes 72/74/70 (Figs. 1A, 1B) are all in common.

16. Regarding claim 5 (as understood): Flesler discloses that the first and second subsets are identical 30 (Figs. 1A, 1B), the electrodes themselves appear to be identical in shape and configuration.

17. Regarding claim 6 (as understood): Flesler discloses that the first subset (within band 22) have no electrodes in common the electrodes on the pyloric sphincter are in a different area considered to not be in common or alternatively, the electrodes within the intestinal apparatus are not in common.

18. Regarding claim 7: Flesler discloses that the implantation site is the stomach (Figs. 1A, 1B) and the electrodes are adapted to be fixed to the stomach (Col. 9, lines 57-61).

19. Regarding claim 9: Flesler discloses implanting on the pylorus, which is a sphincter and considered to be nongastric (Col. 11, lines 19-21).

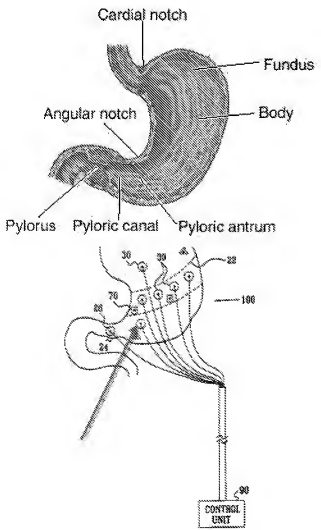
20. Regarding claim 10: Flesler discloses an implant site includes an intestinal site (Fig. 4, Col. 13, lines 50-67), the electric field applied to the intestinal blood supply, considered to be an intestinal site reduces calories absorbed (Col. 14, lines 1-5).

21. Regarding claims 11, 38, 52 and 66: Flesler discloses that the control unit is adapted to drive the first subset not responsive to eating (Col. 3, lines 14-19) and to

drive a second subset responsive to eating (Col. 3, lines 19-25, it is noted that the subsets are not disclosed as differing in location with respect to claim 1, from which claim 11 depends.)

22. Regarding claims 12 and 39, 53 and 67 (as understood): Flesler discloses that the control unit drives the first subset responsive to eating (Col. 4, lines 50-58 and Col. 5, lines 13-24).

23. Claims 8 is are rejected under 35 U.S.C. 102(b) as being anticipated by Flesler et al. (US 6,600,953) given the definition of antrum (http://medical-dictionary.thefreedictionary.com/pyloric+antrum) within the Free Dictionary.com and shown below.



24. Regarding claim 8: Flesler discloses the gastric antrum (Col. 1, lines 31-37) via incorporation by reference of patent number 5,423,872) as well as the general location of the electrode highlighted below, the electrode with the arrow included is within the region

of the pyloric antrum as shown above.

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

26. Claims 13-15 and 40-42, 54-56 and 68-70 (as understood) are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al. (US 6,600,953 in IDS) in view of Foley (US 2004/0162595 in IDS).

27. Regarding claims 13-15 and 40-42, 54-56 and 68-70 (as understood): Flesler discloses the claimed invention however Flesler does not specifically disclose two pairs of electrodes fixed to the antrum of the stomach. Foley however, teaches of a sensor based gastric stimulator (abstract) in which four or more bipolar (considered to be pairs of electrodes) are placed posterior and anterior in the antrum of the stomach (pg. [0075] and Figs. 1, 7, 8) in order to locate a stable position. It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Flesler to include bipolar electrode pairs, as taught by Foley within the antrum of the stomach in order to have a sensing and pacing electrode pair as well as a stable location.

28. Claims 22, 29-32, 42-43, 48-49, 57-58, 62-63, 71-72 and 76-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al. (US 6,600,953 in IDS) in view of Chen et al. (US 5,690,691 in IDS).

29. Regarding claims 22, 31, 43-44, 57-58 and 71-72 (as understood): Flesler discloses the claimed invention except a first frequency component for the first subset of electrodes and a second frequency component for the second subset of electrodes. Chen however discloses a device to aid in peristaltic movement (abstract) in which the upper portion of the stomach is paced at 3 cpm (180Hz) and the lower portion is paced at 12.5 cpm (750 Hz) (Col. 6, lines 43-55). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Flesler to include frequency differences to different parts of the stomach for stimulation purposes, as taught by Chen, in order to aid in peristaltic movement.

30. Regarding claims 29, 30 and 32 and 48-49, 62-63 and 76-77 (as understood): Flesler/Chen disclose the claimed invention except for the first frequency component being less than 10 Hz and the second greater than 10 hz and between 60-100Hz and five time larger than the first component. It would have been obvious to one having ordinary skill in the art at the time the invention was made to the first frequency component being less than 10 Hz and the second greater than 10 hz and between 60-100Hz and five time larger than the first component, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

31. Claims 23, 26, 28, 45, 47, 59, 61, 73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al. (US 6,600,953 in IDS) in view of Chen et al. (US 5,690,691 referred to herein as Chen '691 in IDS) and further in view of Chen et al. (US 2005/0021101 referred to herein as Chen '101 in IDS).

32. Regarding claims 23, 26, 45, 59 and 73 (as understood): Flesler/Chen '691 disclose the claimed invention except the use of a pacing pulse, Chen '101 however teaches of a pacing pulse in order to achieve antergrade electrical stimulation to normalize dysrhythmia (pg. [0074]). Chen '101 also discloses the use of pacing pulses to slow gastric emptying which will slow gastric emptying and result in weight loss (pg. [0080]). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Flesler/Chen '691 to include pacing pulses, as taught by Chen '101 in order to either slow gastric emptying or normalize dysrhythmia.

33. Regarding claims 28, 47, 61 and 75 (as understood): Flesler/Chen '691 discloses the claimed invention except for the first frequency signal following the pacing pulse by 500 ms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to the first frequency signal following the pacing pulse by 500 ms, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

34. Claims 27, 46, 60 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al. (US 6,600,953 in IDS) in view of Chen et al. (US

5,690,691 referred to herein as Chen '691 $_{\text{in IDS}}$) and further in view of Chen et al. (US 2005/0021101 referred to herein as Chen '101 $_{\text{in IDS}}$) and further in view of Ben-Haim et al. (US 2003/0055465).

35. Regarding claims 27, 46, 60 and 74 (as understood):

Flesler/Chen'691/Chen'101 disclose the claimed invention except stimulating during a refractory period. Ben Haim however teaches that applying a signal at a delay following the activation signal (during the refractory period) will extend the refractory period and thus result in decreased propagation of the signal and a reduced the force of contraction (pg. [0229]). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Flesler/Chen'691/Chen'101 to include stimulating during a refractor period, as taught by Ben-Haim in order to extend the refractory period and thus decrease muscle contraction.

36. Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al. (US 6,600,953 $_{\text{in IDS}}$) in view of Chen et al. (US 5,690,691 $_{\text{in IDS}}$) and further in view of Ben-Haim et al. (US 2003/0055465).

37. Regarding claims 24-25: Flesler/Chen discloses the claimed invention except the use of non-excitatory stimulation. Ben-Haim however teaches of using non-excitatory neural stimulation in a smooth muscle controller in order to avoid the propagation of an action potential buy yet modify the excitatory field (pg. [0013]). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Flesler/Chen to include the use of non-excitatory

stimulation in order to avoid the propagation of an action potential buy yet modify the excitatory field.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAULA J. STICE whose telephone number is (571)270-1478. The examiner can normally be reached on Monday - Friday 8AM-5PM, Mst., alternating Friday's.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PAULA J. STICE/
Examiner, Art Unit 3766

/CARL H LAYNO/
Supervisory Patent Examiner, Art Unit 3766